



This is an official CDC Health Advisory

Distributed via Health Alert Network
October 8, 2012
10261-CHU-10-8-12 Mening

Update: Multistate Outbreak of Meningitis and Stroke Associated with Potentially Contaminated Steroid Medication

Summary

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) continue to work closely with state public health departments on a [multistate investigation of fungal meningitis](#) among patients who received an epidural steroid injection. Some of these patients also suffered strokes that may have resulted from their infection. These cases are associated with a potentially contaminated steroid medication prepared by New England Compounding Center (NECC), located in Framingham, Mass. This HAN notice provides updated information about the investigation (including a change in the case definition*), laboratory findings, an expanded voluntary recall of products, and recommendations for clinicians

Background

CDC, in collaboration with FDA, state public health departments, and state boards of pharmacy, has been investigating an ongoing outbreak of meningitis associated with a potentially contaminated steroid medication, preservative-free methylprednisolone acetate (80mg/ml) prepared by New England Compounding Center, located in Framingham, Mass. CDC and state public health departments are actively coordinating outreach to patients who have been exposed to this potentially contaminated medication.

As of October 8, 2012, a total of 105 cases, including 8 deaths, have been reported in 9 states: Florida (4 cases), Indiana (11 cases), Maryland (5 cases, including 1 death), Michigan (21 cases, including 2 deaths), Minnesota (3 cases), North Carolina (2 cases), Ohio (1 case), Tennessee (35 cases, including 4 deaths), and Virginia (23 cases, including 1 death). Fungus has been identified in specimens obtained from at least nine patients, one of whom also had *Propionibacterium acnes*, of unclear clinical significance, isolated from a post-mortem central nervous system specimen. In addition to an *Aspergillus* spp. isolated from a Tennessee patient, the fungus *Exserohilum rostratum* was identified in other patients, indicating the possibility of infections caused by multiple organisms. Fungal meningitis is not transmitted from person to person.

The clinical presentation of infected patients remains consistent with the prior report: onset of symptoms is typically 1 to 4 weeks following injection with a variety of symptoms, including fever, new or worsening headache, nausea, and new neurological deficit (consistent with deep brain stroke). Some of these patients' symptoms were very mild in nature. Cerebrospinal fluid (CSF) obtained from these patients has typically shown elevated white cell count (with a predominance of neutrophils), low glucose, and elevated

protein. As of October 8, no infections resulting from injection into a peripheral joint space have been reported.

Product Recall

On September 26, 2012, the NECC voluntarily recalled the following three lots of methylprednisolone acetate (PF) 80mg/ml:

- Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012
- Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012
- Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013

All infections detected as of October 8 have occurred after injections with methylprednisolone acetate products from one of these lots. At this time, there is no evidence of infection related to other NECC products.

The FDA investigation into the NECC facility is ongoing. On October 5, [FDA reported](#) observing “fungal contamination by direct microscopic examination of foreign matter taken from a sealed vial of methylprednisolone acetate collected from the New England Compounding Center.” Further analysis is ongoing. On October 6, NECC expanded its previous recalls to include all products currently in circulation that were compounded at and distributed from its facility in Framingham, Mass. More information about this recall is available at the [FDA website](#).

Recommendations

Physicians should contact (by phone or in person) **any patient who had an injection (e.g., spinal, joint) after May 21, 2012, using any of the following three recalled lots of preservative-free methylprednisolone acetate (80mg/ml) produced by NECC**, to determine if they are having symptoms:

- Methylprednisolone Acetate (PF) 80mg/ml Injection, Lot# 05212012@68, BUD 11/17/2012
- Methylprednisolone Acetate (PF) 80mg/ml Injection, Lot#06292012@26, BUD 12/26/2012
- Methylprednisolone Acetate (PF) 80mg/ml Injection, Lot# 08102012@51, BUD 2/6/2013

Symptoms that should prompt diagnostic evaluation include: fever, new or worsening headache, neck stiffness, sensitivity to light, new weakness or numbness, increasing pain, redness or swelling at injection site. Some of the symptoms of patients who have ultimately been diagnosed with meningitis have been mild and not classic for meningitis (e.g., new or worsening headache without fever or neck stiffness).

Healthcare professionals should cease use of **any** product produced by NECC, all of which have been recalled.

CDC is currently not asking clinicians to actively contact patients who received other products, beyond the previously listed medications, from NECC to assess for symptoms.

However, clinicians should remain vigilant, and report to the state public health department, any infection identified in a patient known to have received a product from NECC.

CDC has **updated clinician guidance** addressing:

- [Interim Instructions Diagnostic Testing and Specimen Submission to CDC](#)
- [Interim Treatment Guidance for Central Nervous System and/or Parameningeal Infections Associated with Injection of Potentially Contaminated Steroid Products](#)
- [Role of antifungal prophylaxis in asymptomatic patients](#)
- [Role for lumbar puncture in asymptomatic patients](#)

Case Definition

(note: the initial date for an epidural/joint steroid injection has been revised from July 1, 2012, to May 21, 2012).

- A person with meningitis¹ of sub-acute onset (1-4 weeks) following epidural injection after May 21, 2012. **or**
- A person with basilar stroke 1-4 weeks following epidural injection after May 21, 2012², who has not received a diagnostic lumbar puncture, **or**
- A person with evidence of spinal osteomyelitis or epidural abscess at the site of an epidural injection diagnosed 1-4 weeks after epidural injection after May 21, 2012, **or**
- A person with septic arthritis³ diagnosed 1-4 weeks following steroid joint injection after May 21, 2012.

¹Clinically diagnosed meningitis meaning one or more of the following symptoms: headache, fever, stiff neck, or photophobia **and** a CSF profile consistent with meningitis (pleocytosis +/- low glucose, elevated protein).

²These people, if possible, should have a lumbar puncture.

³Clinically diagnosed septic arthritis meaning new or worsening pain with presence of effusion or new or worsening effusion.

Additional Information

- [Multistate Meningitis Outbreak Investigation](#)
- [Case Definition](#)
- [Meningitis and Stroke Associated with Potentially Contaminated Product](#)
- [CDC Website on Fungal Diseases](#)
- [FDA Statement on Fungal Meningitis Outbreak](#)

DHEC contact information for reportable diseases and reporting requirements

Reporting of suspected cases of meningitis is consistent with South Carolina Law requiring the reporting of diseases and conditions to your state or local public health department. (State Law # 44-29-10 and Regulation # 61-20) as per the DHEC 2012 List of Reportable Conditions available at:

<http://www.scdhec.gov/administration/library/CR-009025.pdf>

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512).

Regional Public Health Offices – 2012

Mail or call reports to the Epidemiology Office in each Public Health Region.

Region 1

Anderson, Oconee

220 McGee Road
Anderson, SC 29625
Phone: (864) 260-4358
Fax: (864) 260-5623
Nights / Weekends: 1-866-298-4442

Abbeville, Edgefield, Greenwood, Laurens, McCormick, Saluda

1736 S. Main Street
Greenwood, SC 29646
Phone: 1-888-218-5475
Fax: (864) 942-3690
Nights / Weekends: 1-800-420-1915

Region 2

Greenville, Pickens

PO Box 2507
200 University Ridge
Greenville, SC 29602-2507
Phone: (864) 282-4139
Fax: (864) 282-4373
Nights / Weekends: (864) 809-3825

Cherokee, Spartanburg, Union

PO Box 4217
151 E. Wood Street
Spartanburg, SC 29305-4217
Phone: (864) 596-2227, x- 210
Fax: (864) 596-3443
Nights / Weekends: (864) 809-3825

Region 3

Chester, Lancaster, York

PO Box 817
1833 Pageland Highway
Lancaster, SC 29720
Phone: (803) 286-9948
Fax: (803) 286-5418
Nights / Weekends: 1-866-867-3886

Region 3 (continued)

Fairfield, Lexington, Newberry, Richland

2000 Hampton Street
Columbia, SC 29204
Phone: (803) 576-2749
Fax: (803) 576-2993
Nights / Weekends: 1-888-554-9915

Region 4

Clarendon, Kershaw, Lee, Sumter

PO Box 1628
105 North Magnolia Street
Sumter, SC 29150
Phone: (803) 773-5511
Fax: (803) 775-9941
Nights/Weekends: (803) 458-1847

Chesterfield, Darlington, Dillon, Florence, Marlboro, Marion

145 E. Cheves Street
Florence, SC 29506
Phone: (843) 661-4830
Fax: (843) 661-4859
Nights / Weekends: (843) 601-7051

Region 5

Bamberg, Calhoun, Orangeburg

PO Box 1126
1550 Carolina Avenue
Orangeburg, SC 29116
Phone: (803) 533-7199
Fax: (803) 533-7134
Nights / Weekends: (803) 516-5166

Aiken, Allendale, Barnwell

1680 Richland Avenue, W. Suite 40
Aiken, SC 29801
Phone: (803) 642-1618
Fax: (803) 643-8386
Nights / Weekends: (803) 645-8167

Region 6

Georgetown, Horry, Williamsburg

1931 Industrial Park Road
Conway, SC 29526-5482
Phone: (843) 915-8804
Fax: (843) 365-0085
Nights / Weekends: (843) 340-4754

Region 7

Berkeley, Charleston, Dorchester

4050 Bridge View Drive, Suite 600
N. Charleston, SC 29405
Phone: (843) 953-0047
Fax: (843) 953-0051
Nights / Weekends: (843) 219-8470

Region 8

Beaufort, Colleton, Hampton, Jasper

219 S. Lemacks Street
Walterboro, SC 29488
Phone: (843) 605-3407
Fax: (843) 549-6845
Nights / Weekends: 1-843-441-1091

DHEC Bureau of Disease Control Division of Acute Disease Epidemiology

1751 Calhoun Street
Box 101106
Columbia, SC 29211
Phone: (803) 898-0861
Fax: (803) 898-0897
Nights / Weekends: 1-888-847-0902



www.scdhec.gov

Categories of Health Alert messages:

Health Alert	Conveys the highest level of importance; warrants immediate action or attention.
Health Advisory	Provides important information for a specific incident or situation; may not require immediate action.
Health Update	Provides updated information regarding an incident or situation; unlikely to require immediate action.